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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,262	04/03/2006	Yasuhiro Horiike	RHM-US030695	6359
22919 7590 08/12/2009 GLOBAL IP COUNSELORS, LLP 1233 20TH STREET, NW, SUITE 700 WASHINGTON, DC 20036-2680				
EXAMINER				
KWAK, DEAN P				
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1797				
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08/12/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/595,262

Applicant(s)

HORIIE ET AL.

Examiner

DEAN KWAK

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 19-21 and 23-25 is/are allowed.
6) ☒ Claim(s) 22 and 26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Brotherston et al. (US 6,399,361).

Regarding Claim 22, Brotherston et al. disclose a test chip (e.g., microsystem platform, Abstract) comprising:

- a centrifugal separation tube (e.g., metering capillary, C37/L36 & Fig. 2 (202); Fig. 26 (902));
- a first holding section (e.g., fluid chamber, C37/L48 & Fig. 2 (204)) provided in the bottom of the centrifugal separation tube;
- a measuring section (e.g., read chamber, C11/L48 & Fig. 2 (210); also Fig. 26 (910)) connected to one end of the centrifugal separation tube;
- at least one reagent reservoir (C29/L31 & Fig. 26 (917)) that stores a reagent therein;
- a mixing section (e.g., capillary junction, C29/L27 & Fig. 26 (907)) connected with the reagent reservoir and the measuring section such that the reagent

reservoir is located radially inward from the mixing section relative to an axis of rotation;

- a photodetection path (C11/L50-65) connected to the mixing section, the photodetection path passing a mixed substance obtained by mixing the reagent and the target component; a light inlet connected with the photodetection path, the light inlet introducing light into the photodetection path; and a light outlet connected with the photodetection path, the light outlet removing light after passing through the interior of the photodetection path.

Regarding Claim 22, Brotherston et al. meet all the structural limitations recited by the instant invention. Applicants' preamble recites "for determining a target component in a sample by rotation around a first axis and a second axis of rotation". A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). It is noted that the device disclosed by Brotherston et al. is fully capable of meeting all limitations of said claim.

Regarding limitations recited in Claim 22 which are directed to a manner of operating disclosed apparatus (e.g. "centrifugally separates the target component from the sample by rotating the measuring chip around the first axis of rotation", "non-target components in the sample are introduced in the first holding section by rotation around the first axis of rotation, and

the first holding section holds the non-target components during rotation around the second axis of rotation”, “that measures the target components introduced from the centrifugal separation tube by rotation around the second axis of rotation”, “mixing section mixing the target component introduced from the measuring section by means of another rotation around the first axis of rotation, with the reagent introduced from the reagent reservoir by rotation around the first axis of rotation and/or the second axis of rotation”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
6. Claim 26/22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brotherston et al. (US 6,399,361) in view of Hiroki et al. (JP 2004-109082; see English translation in IDS 04/21/06).

Regarding Claim 26, Brotherston et al. disclose all of the claim limitations as set forth above. However, Brotherston et al. fail to disclose a sampling needle to extract the sample.

Hiroki et al. disclose a microfluidic test chip (e.g., substrate, Fig. 1 (101)) as a blood analyzer, wherein the test chip further comprises a sampling needle (e.g., extraction means, Fig. 1 (103a)) connected with the centrifugal separation tube, the sampling needle serving to extract the sample (to conveniently draw sample, P4/[0006]).

Brotherston et al. and Hiroki et al. are analogous because these references are directed to use of microfluidic device to separate contents by adapting centrifugation (Abstracts).

It would have been obvious to use sampling needle to extract sample, as taught by Hiroki et al., to the test chip, as taught by Brotherston et al., to easily and conveniently draw sample from its location without having to use a transferring device.

Response to Arguments

7. Applicant's arguments filed 06/04/2009 have been fully considered but they are not persuasive.
8. In response to applicant's argument that Brotherston et al. fail to show "such that the reagent reservoir is located radially inward from the mixing section relative to both the first axis of rotation and the second axis of rotation", it is noted that Brotherston et al. disclose a test chip (e.g., microsystem platform, Abstract) comprising a mixing section (e.g., capillary junction, C29/L27 & Fig. 26 (907)) connected with the reagent reservoir (C29/L31 & Fig. 26 (917)) and the measuring section (e.g., read chamber, C11/L48 & Fig. 2 (210); also Fig. 26 (910)) such that the reagent reservoir is located radially inward from the mixing section relative to an axis of rotation (see Fig. 26).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEAN KWAK whose telephone number is 571-270-7072. The examiner can normally be reached on M-TH, 5:30 am - 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

04Aug09

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

/D. K./
Examiner, Art Unit 1797